

# **INSPIREMD, INC.**

FORM	1	0.	-Q
(Quarterly	Re	por	t)

# Filed 11/12/13 for the Period Ending 09/30/13

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Telephone	(857) 453-6553
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	12/31

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#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

#### X **OUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

#### For the quarterly period ended: September 30, 2013

OR

#### TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-35731

# InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

26-2123838 (I.R.S. Employer Identification No.)

800 Bolvston Street, 16 th Floor Boston, MA 02199 (Address of principal executive offices)

(Zip Code)

(857) 453-6553

(Registrant's telephone number, including area code)

Indicate by check mark whether registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  $\Box$ 

Non-accelerated filer  $\Box$ (Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  $\Box$  No  $\boxtimes$ 

The number of shares of the registrant's common stock, \$0.0001 par value, outstanding as of November 11, 2013: 34,512,568.

Accelerated filer  $\Box$ 

Smaller reporting company  $\boxtimes$ 

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### **PART I - FINANCIAL INFORMATION**

**Item 1. Financial Statements** 

#### INSPIREMD, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

#### (U.S. dollars in thousands)

	September 30, 2013		June 30, 2013	
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$	11,440	\$	14,820
Restricted cash		93		93
Accounts receivable:				
Trade		2,128		1,739
Other		447		388
Prepaid expenses		144		272
Inventory		1,392		1,593
Total current assets		15,644		18,905
PROPERTY, PLANT AND EQUIPMENT, net		591		550
NON-CURRENT ASSETS:				
Funds in respect of employees rights upon retirement		436		406
Long term prepaid expenses		143		
Royalties buyout		873		884
Total other non-current assets		1,452		1,290
Total assets	\$	17,687	\$	20,745

The accompanying notes are an integral part of the condensed consolidated financial statements.

#### INSPIREMD, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

#### (U.S. dollars in thousands)

	September 30, 2013		June 30, 2013	
LIABILITIES AND EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accruals:				
Trade	\$	850	\$	831
Other		3,016		3,028
Advanced payment from customers		176		174
Deferred revenues				10
Total current liabilities		4,042		4,043
LONG-TERM LIABILITIES:				
Liability for employees rights upon retirement		637		600
Total long-term liabilities		637		600
COMMITMENTS AND CONTINGENT LIABILITIES				
(Note 9)				
Total liabilities		4,679		4,643
EQUITY :				
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 33,965,950 and				
33,888,845 shares issued and outstanding at September 30, 2013 and June 30, 2013,				
respectively		3		3
Additional paid-in capital		89,930		89,079
Accumulated deficit		(76,925)		(72,980)
Total equity		13,008		16,102
Total liabilities and equity	\$	17,687	\$	20,745

The accompanying notes are an integral part of the condensed consolidated financial statements.

### INSPIREMD, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

### (U.S. dollars in thousands, except share and per share data)

	Three months ended September 30,			
		2013		2012
REVENUES	\$	1,552	\$	509
COST OF REVENUES		750		230
GROSS PROFIT		802		279
OPERATING EXPENSES:				
Research and development		1,544		946
Selling and marketing		830		402
General and administrative (including \$795 and \$819 of share-based compensation for the 3				
months ended September 30, 2013 and 2012, respectively)		2,313		2,212
Total operating expenses		4,687		3,560
LOSS FROM OPERATIONS		(3,885)		(3,281)
FINANCIAL EXPENSES, net:				
Interest on convertible loan and revaluation of contingently redeemable warrants and others		77		4,213
Other financial expenses (income)		(20)		5
LOSS BEFORE INCOME TAXES		(3,942)		(7,499)
TAX EXPENSES		3		7
NET LOSS	\$	(3,945)	\$	(7,506)
NET LOSS PER SHARE - basic and diluted	\$	(0.12)	\$	(0.44)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted		33,959,773		17,074,235

The accompanying notes are an integral part of the condensed consolidated financial statements.

#### INSPIREMD, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(U.S. dollars in thousands)

	3 months ended September 30,			
		2013		2012
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	\$	(3,945)	\$	(7,506)
Adjustments required to reconcile net loss to net				
cash used in operating activities:				
Depreciation and amortization		50		34
Change in liability for employees right upon retirement		37		40
Financial expenses		75		3,984
Share-based compensation expenses		851		931
Changes in operating asset and liability items:				
Decrease (increase) in prepaid expenses		(15)		37
Decrease (increase) in trade receivables		(389)		746
Increase in other receivables		(59)		(144)
Decrease in inventory on consignment				41
Decrease (increase) in inventory on hand		201		(332)
Increase in trade payables		19		115
Decrease in deferred revenues		(10)		
Decrease in other payables and advance payment from customers		(87)		(302)
Net cash used in operating activities		(3,272)		(2,356)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of property, plant and equipment		(80)		(35)
Amounts funded in respect of employee rights upon retirement, net		(30)		(22)
Net cash used in investing activities		(110)		(57)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Exercise of options and warrants				432
Net cash provided by financing activities				432
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS		2		(6)
DECREASE IN CASH AND CASH EQUIVALENTS		(3,380)		(1,987)
BALANCE OF CASH AND CASH EQUIVALENTS		(0,000)		(-,,, , , , , , , , , , , , , , , , , ,
AT BEGINNING OF THE PERIOD		14,820		10,284
BALANCE OF CASH AND CASH EQUIVALENTS		11,020	-	10,201
AT END OF THE PERIOD	\$	11,440	\$	8,297
AT END OF THE PERIOD	Ŷ	,	Ψ	0,277

The accompanying notes are an integral part of the condensed consolidated financial statements.

#### NOTE 1 - DESCRIPTION OF BUSINESS

InspireMD, Inc., a Delaware corporation (the "Company"), together with its subsidiaries, is a medical device company focused on the development and commercialization of its proprietary stent platform technology, MGuard<sup>TM</sup>. MGuard provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent. The Company's initial products are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). The Company markets its products through distributors in international markets, mainly in Europe and Latin America.

Due to the Security and Loan Agreement as described in Note 12, the Company believes that it has sufficient cash to continue its operations into 2015. However, depending on the operating results in 2014, the Company may need to obtain additional cash in 2015 to continue to fund its operations.

#### **NOTE 2 - BASIS OF PRESENTATION**

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the year ended June 30, 2013, as found in the Company Report on Form 10-K, filed with the Securities and Exchange Commission on September 17, 2013. The balance sheet for June 30, 2013 was derived from the Company's audited financial statements for the year ended June 30, 2013. The results of operations for the three months ended September 30, 2013 are not necessarily indicative of results that could be expected for the entire fiscal year.

#### NOTE 3- EQUITY:

- a. During the three months ended September 30, 2013, the Company issued a total of 77,103 shares of its common stock in connection with the exercise of 77,103 options, for consideration of less than \$1,000.
- b. During the three months ended September 30, 2013, a director of the Company was granted options to purchase shares of the Company's common stock. See Note 9.

#### NOTE 4- NET LOSS PER SHARE:

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential share issuances of common stock upon the exercise of share options, warrants, convertible loans and restricted stock as the effect is anti-dilutive.

For the three month periods ended September 30, 2013 and 2012, all shares of common stock underlying outstanding options, warrants, convertible loans and restricted stock have been excluded from the calculation of the diluted loss per share since their effect was anti-dilutive. The total number of shares of common stock related to outstanding options, warrants, convertible loans and restricted stock excluded from the calculations of diluted loss per share were 8,180,669 and 8,047,714 for the three month periods ended September 30, 2013 and 2012, respectively.

#### NOTE 5 - FAIR VALUE MEASURMENT:

#### Financial Assets and Liabilities Not Measured Using Fair Value Method

The carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments. If measured at fair value in the financial statements, these financial instruments would be classified as Level 3 in the fair value hierarchy. As of September 30, 2013, the carrying amount of cash and cash equivalents, accounts receivable, other current assets and accounts payables and accrued expenses approximates their fair values due to the short-term maturities of these instruments.

### NOTE 6 - INVENTORY:

	September 2013	30,	June 3 2013	,
	(\$	in thou	isands)	
Finished goods	\$	551	\$	364
Work in process		707		1,111
Raw materials and supplies		134		118
	\$ 1	,392	\$	1,593

As of September 30, 2013 and June 30, 2013, the Company had provisions for slow moving inventory of approximately \$356,000 and \$379,000, respectively .

## NOTE 7 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	-	September 30, 2013		une 30, 2013
	(\$ in thousand			ls)
Employees and employee institutions	\$	729	\$	626
Accrued vacation and recreation pay		305		313
Accrued clinical trial expenses		760		513
Provision for sales commissions		148		205
Accrued expenses		1,051		1,343
Other		23		28
	\$	3,016	\$	3,028

#### NOTE 8 - FINANCIAL EXPENSES, NET:

	3 Months ended September 30,			
	2013		2012	
	(\$ in thousands)			
Bank commissions	\$	11	\$	9
Interest income		(2)		(9)
Exchange rate differences		(29)		5
Interest expense (including debt issuance costs)				988
Change in fair value of warrants, embedded derivatives and				
other		77		3,225
	\$	57	\$	4,218

#### **NOTE 9 - RELATED PARTIES:**

On September 3, 2013, the board of directors of the Company appointed a new director with a term expiring at the Company's 2014 annual meeting of stockholders.

In connection with his appointment, the director was granted an option to purchase 125,000 shares of the Company's common stock at an exercise price of \$2.12 per share (the "\$2.12 Option"). The \$2.12 Option is exercisable in three equal annual installments beginning on the one-year anniversary of the date of grant.

In calculating the fair value of the \$2.12 Option, the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility of 68%-69%; and risk-free interest rate of 1.84%- 2.15%. The option has a term of 10 years from the date of grant, and the fair value of the option on the date of grant, using the Black-Scholes option-pricing model, was approximately \$164,000.

#### NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES:

#### a. Commitment

In March 2010, the Company entered into a license agreement (the "License Agreement") to use a stent design ("MGuard Prime") developed by a company owned by a former director of InspireMD Ltd. (the "Licensor"). Pursuant to the agreement, the Licensor was entitled to receive royalty payments of 7% of net sales outside the United States and, for sales within the U.S., royalty payments as follows: 7% of the first \$10,000,000 in net sales and 10% of net sales exceeding \$10,000,000.

On October 20, 2012, the Company, InspireMD Ltd. and the Licensor entered into an amendment (the "First Amendment") to the License Agreement, pursuant to which, amongst other things, the Licensor agreed to reduce the royalty owed with respect to sales of MGuard Prime to 2.9% of all net sales both inside and outside the U.S. in exchange for (i) InspireMD Ltd. waiving \$85,000 in regulatory fees for the CE Mark that were owed by the Licensor to InspireMD Ltd., (ii) InspireMD Ltd. making full payment of royalties in the amount of \$205,587 due to the Licensor as of September 30, 2012 and (iii) 215,000 shares of the Company's common stock, that were valued at the closing price of the common stock on October 19, 2012 at \$8.20 per share. The total amount paid to the Licensor was valued at \$1,848,000, inclusive of the shares issued as well as the \$85,000 waiver, and was allocated in the consolidated financial statements for the year ended June 30, 2013 as follows: approximately \$930,000 was allocated to royalties' buyout and approximately \$918,000 was allocated to "research and development" expenses based on the MGuard Prime registration status in various territories. The royalties' buyout amortization is calculated using the economic pattern of the Company's estimated future revenues over the estimated useful life of the royalties' buyout. The amortization is recorded in "Cost of Revenues" in the consolidated statements of operations.

On August 22, 2013, the Company, InspireMD Ltd. and the Licensor entered into an amendment to the License Agreement (the "Second Amendment"), pursuant to which the Company and the Licensor agreed to amend the royalty fee from 2.9% of all net sales during the term of the agreement to (i) 2% of the first \$10.56 million of net sales from July 1, 2013 through June 30, 2015, provided that the Company makes an advance royalty payment of \$192,000 on the date of the amendment, (ii) 2.5% of net sales in excess of \$10.56 million from July 1, 2013 through June 30, 2015, payable within 45 days of June 30, 2015, and (iii) 2.9% of all net sales beginning on July 1, 2015. The above referenced advance royalty payment has been included in long term prepaid expenses.



#### b. Litigation

In July 2012, a purported assignee of options in InspireMD Ltd. submitted a statement of claim against the Company, InspireMD Ltd., and the Company's former CEO and President for a declaratory and enforcement order that it is entitled to options to purchase 83,637 shares of the Company's common stock at an exercise price of \$0.76 per share. In January 2013, the defendants submitted a motion to dismiss the claim or move it to the Economic Department to the Tel Aviv District Court due to the lack of material jurisdiction of the court where the claim was filed. The court accepted such motion and transferred the case to the Economic Department to the Tel Aviv District Court. In April 2013, the Company's former CEO and President submitted a motion to dismiss the claim against them on the grounds that the letter of claims does not present any legal case against any of them. The first hearing in the case was held on April 23, 2013, during which the judge suggested the parties try to solve the dispute through mediation. On July 3, 2013, the parties held a first mediation meeting. After considering the views of its legal counsel as well as other factors, the Company's management believes that a loss to the Company is neither probable nor in an amount or range of loss that is estimable.

In December 2012, a former service provider of InspireMD GmbH filed a claim with the Labor Court in Buenos Aires, Argentina in the amount of \$193,378 plus interest (6% in dollars or 18.5% in pesos), social benefits, legal expenses and fees (25% of the award) against InspireMD Ltd. and InspireMD GmbH. The court dismissed the claim based on a lack of jurisdiction. Following this dismissal, the plaintiff appealed the ruling. While the Company believes that this claim is wholly without merit, the Company's management, after considering the views of its legal counsel as well as other factors, recorded a provision of \$250,000 in the financial statements for the quarter ended December 31, 2012. The Company's management estimates that the ultimate resolution of this matter could result in a loss of up to \$80,000 in excess of the amount accrued.

#### c. Liens and pledges

As of September 30, 2013, the Company had fixed liens aggregating \$93,000 to Bank Mizrahi in connection with the Company's credit cards.

#### NOTE 11 - ENTITY WIDE DISCLOSURE:

The Company operates in one reportable segment.

Disaggregated financial data is provided below as follows:

- (1) Revenues by geographic area and
- (2) Revenues from principal customers.

Revenues are attributed to geographic areas based on the location of the customers. The following is a summary of revenues by geographic areas:

		3 months ended September 30,			
	2	2013 201			
	(\$ in thousands)				
Russia	\$	454 \$	24		
Spain		162	101		
South Africa		59	57		
Israel		57	75		
Other		820	252		
	\$	1,552 \$	509		

The following is a summary of revenues by principal customers:

	3 months ended September 30,				
	2013 2012				
Customer A	29%	5%			
Customer B	10%	20%			
Customer C	4%	<u>11</u> %			
Customer D	4%	15%			

All tangible long-lived assets are located in Israel.

#### NOTE 12 - SUBSEQUENT EVENTS:

#### a. Rights agreement

On October 22, 2013, the Board adopted a stockholder rights plan (the "Rights Plan") and declared a dividend distribution to the Company's stockholders of record at the close of business on November 15, 2013, of one preferred stock purchase right (a "Right") for each outstanding share of common stock that will entitle the registered holder to purchase from the Company one one-thousandth (1/1,000) of a share of Series A Preferred Stock at a purchase price of \$21.00 per one one-thousandth (1/1,000) of a share, subject to adjustment.

Initially, the Rights will not be exercisable and will trade with the Company's shares of common stock.

Under the Rights Plan, the Rights will generally become exercisable only if a person or group acquires beneficial ownership of 15% or more of the Company's common stock in a transaction not approved by the Company's Board. In that situation, each holder of a Right (other than the acquiring person, whose Rights will become void and will not be exercisable) will be entitled to purchase, at the then-current exercise price, additional shares of common stock having a value of twice the exercise price of the Right. In addition, if the Company's common stock, each holder of a Right would then be entitled to purchase at the then-current exercise price, shares of the acquiring company's stock, having a value of twice the exercise price of the Right.

The Company's Board may redeem the Rights for a nominal amount at any time before an event that causes the Rights to become exercisable. Under the terms of the Rights Plan, it will expire on October 22, 2014.

#### b. Security and Loan Agreement

On October 23, 2013, the Company and InspireMD Ltd. entered into a Loan and Security Agreement (the "Loan and Security Agreement"), pursuant to which a lender made a term loan to the Company and InspireMD Ltd. in the aggregate amount of \$10 million (the "Loan"). The interest on the Loan is determined on a daily basis at a variable rate equal to the greater of either (i) 10.5%, or (ii) the sum of (A) 10.5%, plus (B) the prime rate minus 5.5%. Payments under the Loan and Security Agreement are for the interest portion only for 9 months, followed by 30 monthly payments of principal and interest through the scheduled maturity date on February 1, 2017. The Company and InspireMD Ltd.'s obligations under the Loan and Security Agreement are secured by a grant of a security interest in all of the Company's and InspireMD Ltd.'s assets (other than their intellectual property).

The Company is permitted to prepay all or a portion of the Loan. However, any prepayments of the Loan will be subject to a penalty of (i) 2%, if the prepayment occurs within 12 months of the Loan being requested by the Company and InspireMD Ltd. (the "Advance Date"), (ii) 1%, if the prepayment occurs between 12 and 24 months after the Advance Date, and (iii) 0.5%, if the prepayment occurs more than 24 months after the Advance Date. The Company and InspireMD Ltd. will also pay the lender an aggregate end of term charge of \$500,000 when the Loan is paid in full or matures.

The Loan and Security Agreement contains a variety of standard events of default, as well as the following events: (i) the occurrence of a material adverse effect (as defined in the Loan and Security Agreement), (ii) breach of covenants and (iii) finding of a judgment against the Company or InspireMD Ltd. of at least \$1 million.

The Loan and Security Agreement contains standard, as well as the following, covenants: (i) a prohibition on the incurrence of additional indebtedness or liens, subject to certain exemptions, (ii) a prohibition on making investments in third parties and (iii) a prohibition on entering a change of control transaction.

The lender has the right to invest up to \$1 million in any future financing of the Company or InspireMD Ltd. that is in the aggregate amount of at least \$10 million.

#### c. Warrant Agreement

On October 23, 2013, in connection with the Loan and Security Agreement, the Company issued the lender a warrant to purchase 168,351 shares of common stock at a per share exercise price of \$2.97 (the "Warrant"). The Warrant is immediately exercisable and has a five year term. The Warrant may also be exercised on a cashless basis. The exercise price of the Warrant and the number of shares issuable upon exercise of the Warrant are subject to adjustments for stock splits, combinations or similar events.

Upon the occurrence of a transaction involving a change of control of the Company in which the consideration is either all cash or securities that are either registered for sale on an exchange or quotation system or otherwise unrestricted, the Warrant, to the extent not previously exercised, may be exchanged, at the holder's request, for the consideration the holder would have received, less the exercise price, had the holder exercised the Warrant immediately prior to the change of control. For all other changes of control of the Company, the Warrant will be assumed by the successor or surviving entity with similar rights to the Warrant as if it had been exercised immediately prior to the change of control. The Warrant contains piggyback registration rights for the shares of common stock underlying the Warrant.

#### d. Security Documents

On October 23, 2013, InspireMD Ltd. issued the lender a Fixed Charge Debenture and a Floating Charge Debenture (collectively, the "Israeli Security Agreements") in order to create a security interest in all the assets and property of InspireMD Ltd. securing the Company's and InspireMD Ltd.'s obligations under the Loan and Security Agreement. In addition, on October 23, 2013, the Company entered into a Deposit Account Control Agreement with the lender and Bank Leumi USA (the "Deposit Account Control Agreement") in order to perfect the lender's security interest in the Company's bank account. Pursuant to the Loan and Security Agreement, the Israeli Security Agreements and the Deposit Account Control Agreement, the Company's obligations to the lender are secured by a first priority perfected security interest in all of the assets and properties of the Company and InspireMD Ltd., other than the intellectual property of the Company and InspireMD Ltd. In addition, the Company is obligated to enter into an account control agreement for its account with Bank of America Merrill Lynch within 60 days of October 23, 2013.

#### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Unless the context requires otherwise, references in this Form 10-Q to the "Company," "InspireMD," "we," "our" and "us" refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries.

#### **Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains "forward-looking statements," which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or our good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- our ability to complete clinical trials as anticipated and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- disputes over ownership of intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;
- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that the MGuard<sup>™</sup> technology is an attractive alternative to other procedures and products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- loss of a key customer or supplier;
- technical problems with our research and products and potential product liability claims;
- adverse economic conditions;
- adverse federal, state and local government regulation, in the United States, Europe, Asia or Israel;
- price increases for supplies and components;
- inability to carry out research, development and commercialization plans; and
- loss or retirement of key executives and research scientists.

For a discussion of these and other risks that relate to our business and investing in our common stock, you should carefully review the risks and uncertainties described under the heading "Part II – Item 1A. Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the twelve month period ended June 30, 2013, and those described from time to time in our future reports filed with the Securities and Exchange Commission. The forward-looking statements contained in this Quarterly Report on Form 10-Q are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

#### Overview

We are a medical device company focused on the development and commercialization of our proprietary stent platform technology, MGuard. MGuard provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent. Our initial products are marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

We effectuated a one-for-four reverse stock split of our common stock on December 21, 2012. Our authorized shares of common stock were not adjusted as a result of this reverse stock split. All share and related option and warrant information presented in the following discussion and analysis of our financial condition and results of operations and the accompanying consolidated interim financial statements have been retroactively adjusted to reflect the reduced number of shares outstanding which resulted from this action.

On September 16, 2013, our board of directors approved a change in our fiscal year-end from June 30 to December 31, effective December 31, 2013.

#### **Recent Events**

On October 23, 2013, we entered into a loan and security agreement, pursuant to which we received a loan of \$10 million. Interest on the loan is determined on a daily basis at a variable rate equal to the greater of either (i) 10.5%, or (ii) the sum of (A) 10.5% plus (B) the prime rate minus 5.5%. Payments under the loan and security agreement are interest only for 9 months, followed by 30 monthly payments of principal and interest through the scheduled maturity date on February 1, 2017. Our obligations under the loan and security agreement are secured by a grant of a security interest in all of our assets (other than our intellectual property). In addition, in connection with the loan and security agreement, we issued the lender a five year warrant to purchase 168,351 shares of our common stock at a per share exercise price of \$2.97.

#### **Critical Accounting Policies**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are more fully described in both (i) the Management's Discussion and Analysis of Financial Condition and Results of Operations section and (ii) Note 2 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended June 30, 2013. There have not been any material changes to such critical accounting policies since June 30, 2013.

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar ("\$" or "dollar"). Accordingly, our currency is the dollar.

#### **Results of Operations**

#### Three months ended September 30, 2013 compared to three months ended September 30, 2012

*Revenues*. For the three months ended September 30, 2013, revenue increased by approximately \$1.1 million, or 204.9%, to approximately \$1.6 million from approximately \$0.5 million during the same period in 2012. This increase was predominantly driven by an increase in sales volume of approximately \$1.0 million, or approximately 192.5%, with price increases to our repeat distributors driving the remaining increase of approximately \$0.1 million, or 12.4%. The \$1.0 million increase in sales volume reflects the positive impact of recent steps taken to stabilize the global distribution strategy and the early success of targeted selling activities in Brazil as well as select European countries.

With respect to regions, the increase in revenue was mainly attributable to an increase of approximately \$0.8 million in revenue from our distributors in Europe and an increase of approximately \$0.3 million in revenue from our distributors in Latin America.

*Gross Profit*. For the three months ended September 30, 2013, gross profit (revenue less cost of revenues) increased 187.5%, or approximately \$0.5 million, to approximately \$0.8 million from approximately \$0.3 million during the same period in 2012. The increase in gross profit is attributable to an increase in revenue of approximately \$1.1 million, as described above, partially offset by an increase in cost of revenues of approximately \$0.5 million, which was composed of material and labor costs of approximately \$0.4 million associated with our increased sales and approximately \$0.2 million of non-recurring expenses related to the consolidation of our manufacturing facilities, partially offset by a decrease of approximately \$0.1 million in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) decreased from 54.8% in the three months ended September 30, 2012 to 51.7% in the three months ended September 30, 2013. If the non-recurring effects of the consolidation of our manufacturing facilities in the three months ended September 30, 2013, are removed, gross margin for the three months ended September 30, 2013 would have been 63.1%.

		Three months ended September 30,				
	2013		2	2012		
		(\$ in thousands)				
Gross Profit	\$	802	\$	279		
Non-recurring expenses		178		-		
Gross profit excluding non-recurring expenses	\$	980	\$	279		

*Research and Development Expenses*. For the three months ended September 30, 2013, research and development expenses increased 63.2%, or approximately \$0.6 million, to approximately \$1.5 million, from approximately \$0.9 million during the same period in 2012. This increase in research and development expenses resulted primarily from an increase of approximately \$0.1 in related travel expenses and \$0.8 million in clinical trial expenses associated with our U.S Food and Drug Administration trial moving from the pre-clinical stage to the set-up phase, triggering costs associated with the selection and qualification of trial sites, and contract research organization management fees, among others. This increase in research and development expenses, however, was partially offset by a decrease of \$0.2 million in expenses associated with our MASTER trial, which is near conclusion, and a decrease of approximately \$0.1 million in expenditures related to the development of the MGuard Carotid product. Research and development expenses as a percentage of revenue decreased to 99.5% for the three months ended September 30, 2013, from 185.9% in the same period in 2012. Research and development expenses related to continue to increase sharply, as we received an approval with conditions to commence the trial on April 19, 2013 and had the first patient enrolled in July 2013.

Selling and Marketing Expenses. For the three months ended September 30, 2013, selling and marketing expenses increased 106.5%, or approximately \$0.4 million, to approximately \$0.8 million, from approximately \$0.4 million during the same period in 2012. The increase in selling and marketing expenses resulted primarily from an increase of approximately \$0.3 million in salaries, as we expanded our sales activities worldwide, and an increase of approximately \$0.1 million in miscellaneous expense. Much of these sales initiatives were driven by our efforts to capitalize on the publication of the MASTER trial results, which represented our first randomized data related to our MGuard technology, and efforts to support our new direct sales channels in key European countries. Selling and marketing expenses as a percentage of revenue decreased to 53.5% in the three months ended September 30, 2013 from 79.0% in the same period in 2012.

*General and Administrative Expenses*. For the three months ended September 30, 2013, general and administrative expenses increased 4.6%, or approximately \$0.1 million, to approximately \$2.3 million from approximately \$2.2 million during the same period in 2012. The increase in general and administrative expenses resulted primarily from an increase of approximately \$0.3 million in salaries (which predominately relates to the hiring of our new chief executive officer and our vice president of corporate development) and an increase of approximately \$0.1 million in miscellaneous expenses. This increase was partially offset by a decrease in bad debt expense of approximately \$0.2 million and a decrease of approximately \$0.1 million in audit fees. General and administrative expenses as a percentage of revenue decreased to 149.0% in the three months ended September 30, 2013 from 434.6% in the same period in 2012.

*Financial Expenses*. For the three months ended September 30, 2013, financial expenses decreased 98.6%, or approximately \$4.1 million, to approximately \$0.1 million from approximately \$4.2 million during the same period in 2012. The decrease in financial expenses resulted primarily from the absence of any non-cash revaluations of our warrants or amortization expenses during the three months ended September 30, 2013. In contrast, during the three months ended September 30, 2012, we recognized approximately \$3.2 million of financial expense pertaining to the non-cash revaluation of certain of our warrants due to our stock price increasing from \$4.24 to \$9.08 during such period and approximately \$1.0 million of amortization expense pertaining to our previously outstanding senior convertible debentures and their related issuance costs (of which approximately \$0.8 million represented the non-cash amortization of the discount of the convertible debentures and their related issuance costs). This decrease in expenses was partially offset by approximately \$0.1 million of non-cash expense pertaining to our obligation to issue shares of common stock without new consideration to the investors in our March 2011 private placement due to certain anti-dilution rights held by such stockholders. Financial expense as a percentage of revenue decreased from 828.7% in the three months ended September 30, 2012, to 3.7% in the same period in 2013. If the non-cash effects of the warrant revaluation and amortization expense in the three months ended September 30, 2012, as well as the non-cash effects of the anti-dilution rights in the three months ended September 30, 2013, are removed, financial expenses for the three months ended September 30, 2012, would have totaled approximately \$0.2 million, as compared to approximately \$20,000 of financial income for the three months ended September 30, 2013, resulting in a decrease of approximately \$0.2 million

	Three months ended September 30,				
	2	013		2012	
	(\$ in thousands)				
Financial expenses	\$	57	\$	4,218	
Non-cash expenses:					
Anti-dilution rights		77		-	
Revaluation of warrants		-		3,225	
Amortization expense				752	
Total non-cash expenses		77		3,977	
Financial expenses (income) excluding non-cash expenses	\$	(20)	\$	241	

*Tax Expenses.* For the three months ended September 30, 2013, tax expenses decreased approximately \$4,000 to approximately \$3,000 for the three months ended September 30, 2013, from approximately \$7,000 during the same period in 2012.

*Net Loss*. Our net loss decreased by approximately \$3.6 million, or 47.4%, to approximately \$3.9 million for the three months ended September 30, 2013 from approximately \$7.5 million during the same period in 2012. The decrease in net loss resulted primarily from a decrease of approximately \$4.1 million in financial expenses, of which approximately \$3.9 million were non-cash (see above for explanation), and an increase of approximately \$0.6 million in gross profit (see above for explanation), partially offset by an increase of approximately \$1.1 million in operating expenses (see above for explanation). If the non-cash effects of the warrant revaluation and amortization expense in the three months ended September 30, 2012, as well as the anti-dilution rights in the three months ended September 30, 2013 are removed, our net loss would be approximately \$3.5 million for the three months ended September 30, 2012, as compared to a net loss of approximately \$3.9 million for the same period in 2013, resulting in an increase of approximately \$0.4 million, or 9.6%.

#### Liquidity and Capital Resources

On April 16, 2013, we consummated an underwritten public offering, pursuant to which we sold 12.5 million shares of common stock at a public offering price of \$2.00 per share. In connection with this offering, we received net proceeds of approximately \$22.6 million, after deducting the underwriters' commissions and offering expenses.

Due to the underwritten public offering of our common stock in April 2013, pursuant to which we received net proceeds of approximately \$22.6 million, the exchange and amendment agreement pursuant to which, as described below, we fully satisfied our obligations under our senior secured convertible debentures due April 15, 2014 in the prior principal amount of \$11.7 million and our receipt of net proceeds of approximately \$9.9 million in connection with the loan and security agreement we entered into in October 2013, we believe that we have sufficient cash to continue our operations into 2015. However, depending on the operating results in 2014, we may need to raise additional funds in 2015 to continue financing our operations.

#### Three months ended September 30, 2013 compared to three months ended September 30, 2012

*General*. At September 30, 2013, we had cash and cash equivalents of approximately \$11.4 million, as compared to \$14.8 million as of June 30, 2013. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and sales. Our cash requirements are generally for clinical trials, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was approximately \$3.3 million for the three months ended September 30, 2013 and \$2.4 million for the same period in 2012. The principal reasons for the usage of cash in our operating activities for the three months ended September 30, 2013 include a net loss of approximately \$3.9 million and an increase in working capital of approximately \$0.3 million, offset by approximately \$0.9 million in non-cash share-based compensation that was largely paid to our directors and chief executive officer.

Cash used in our investing activities was approximately \$110,000 during the three months ended September 30, 2013, compared to approximately \$57,000 during the same period in 2012. The principal reason for the increase in cash used in investing activities during 2013 was the purchase of property, plant and equipment of approximately \$80,000 (primarily new manufacturing equipment and leasehold improvements for our production facilities) and the funding of employee retirement funds of approximately \$30,000.

There was no cash generated or used by financing activities for the three months ended September 30, 2013, compared to \$0.4 million generated during the same period in 2012. The principal source of cash generated from financing activities during the three months ended September 30, 2012 was approximately \$0.4 million of funds received from the exercise of options and warrants.

As of September 30, 2013, our current assets exceeded our current liabilities by a multiple of 3.9. Current assets decreased approximately \$3.3 million during the three month period, mainly due to cash used in operations, and current liabilities remained flat during the period. As a result, our working capital surplus decreased by approximately \$3.3 million to approximately \$1.6 million at September 30, 2013.

#### **Off Balance Sheet Arrangements**

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

#### **Recent Accounting Pronouncements**

None.

#### **Factors That May Affect Future Operations**

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

#### **Item 4. Controls and Procedures**

#### Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of September 30, 2013, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of September 30, 2013.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the three months ended September 30, 2013 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **PART II - OTHER INFORMATION**

#### **Item 1. Legal Proceedings**

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not a party to any material litigation nor are we aware of any such threatened or pending litigation.

#### Item 1A. Risk Factors

During the three months ended September 30, 2013, there were no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the fiscal year ended June 30, 2013, except for the following:

#### **Risks Related to Our Organization and Our Common Stock**

# Our corporate charter and bylaws, our rights agreement and Delaware law contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders.

Attempts to acquire control of us may also be discouraged, delayed or prevented by our stockholder rights agreement. Pursuant to the rights plan, we will issue one preferred share purchase right for each outstanding share of common stock at the close of business on November 15, 2013. Initially, the rights will not be exercisable and will trade with our shares of common stock. The rights will generally become exercisable if a person or group acquires beneficial ownership of 15% or more of our common stock in a transaction not approved by our board of directors. In that situation, each holder of a right (other than the acquiring person, whose rights will become void and will not be exercisable) will be entitled to purchase, at the then-current exercise price, additional shares of common stock having a value of twice the exercise price of the right. In addition, if we are acquired in a merger or other business combination after an unapproved party acquires more than 15% of our common stock, each holder of a right would then be entitled to purchase at the then-current exercise price, shares of the acquiring company's stock, having a value of twice the exercise price of the right.

In addition, we are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless (i) prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; (ii) the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

#### **Risks Related to our Indebtedness**

Our obligations under our term loan are secured by substantially all of our assets, so if we default on those obligations, the lender could foreclose on our assets. As a result of these security interests, such assets would only be available to satisfy claims of our general creditors or to holders of our equity securities if we were to become insolvent at a time when the value of such assets exceeded the amount of our indebtedness and other obligations. In addition, the existence of these security interests may adversely affect our financial flexibility.



The lender under our term loan has a security interest in substantially all of our assets and those of InspireMD Ltd., our wholly-owned subsidiary. As a result, if we default under our obligations to the lender, the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, the lender would have a prior right to substantially all of our assets to the exclusion of our general creditors. In that event, our assets would first be used to repay in full all indebtedness and other obligations secured by the lender, resulting in all or a portion of our assets being unavailable to satisfy the claims of any unsecured indebtedness. Only after satisfying the claims of any unsecured creditors would any amount be available for our equity holders.

The pledge of these assets and other restrictions may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged under the term loan, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

Our loan and security agreement contains customary events of default. In addition, an event of default will include the occurrence of a circumstance that would reasonably be expected to have a material adverse effect upon (i) our business, operations, properties, assets, prospects or condition (financial or otherwise), (ii) our ability to perform our obligations under the agreement and any related loan documents or (iii) the collateral, the lender's liens on the collateral or the priority of such liens.

#### We have a substantial amount of indebtedness, which may adversely affect our cash flow and our ability to operate our business.

Pursuant to the terms of our loan and security agreement, the lender made a term loan to us and InspireMD Ltd. in aggregate amount of \$10 million. We are required to make monthly payments of interest until August 31, 2014, monthly payments of principal and interest after such date, and repay the entire principal balance and any unpaid interest on February 1, 2017.

The terms of our term loan could have negative consequences to us, such as:

- we may be unable to obtain additional financing to fund working capital, operating losses, capital expenditures or acquisitions on terms acceptable to us, or at all;
- the amount of our interest expense may increase because our term loan has a variable rate of interest at any time that the prime rate, as reported in the Wall Street Journal, is above 5.5%;
- we will need to use a substantial portion of our cash flows to pay principal and interest on our term loan, which will reduce the amount of money we have for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other business activities;
- we may have a higher level of debt than some of our competitors, which may put us at a competitive disadvantage;
- we may be unable to refinance our indebtedness on terms acceptable to us, or at all; and
- we may be more vulnerable to economic downturns and adverse developments in our industry or the economy in general.

Our ability to meet our expenses and debt obligations will depend on our future performance, which will be affected by financial, business, economic, regulatory and other factors. We will be unable to control many of these factors, such as economic conditions. We cannot be certain that our earnings will be sufficient to allow us to pay the principal and interest on our debt and meet any other obligations. If we do not have enough money to service our debt, we may be required, but unable to refinance all or part of our existing debt, sell assets, borrow money or raise equity on terms acceptable to us, if at all, and the lender could foreclose on its security interests and liquidate some or all of our assets.

# Our loan and security agreement contains covenants that could limit our financing options and liquidity position, which would limit our ability to grow our business.

Covenants in our loan and security agreement impose operating and financial restrictions on us. These restrictions prohibit or limit our ability, and the ability of InspireMD Ltd., to, among other things:

- pay cash dividends to our stockholders;
- redeem or repurchase our common stock or other equity;
- incur additional indebtedness;
- permit liens on assets;
- make certain investments (including through the acquisition of stock, shares, partnership or limited liability company interests, any loan, advance or capital contribution)
- sell, lease, license, lend or otherwise convey an interest in a material portion of our assets; and
- cease making public filings under the Securities Exchange Act of 1934, as amended.

These restrictions may limit our ability to obtain additional financing, withstand downturns in our business or take advantage of business opportunities. Moreover, additional debt financing we may seek, if permitted, may contain terms that include more restrictive covenants, may require repayment on an accelerated schedule or may impose other obligations that limit our ability to grow our business, acquire needed assets, or take other actions we might otherwise consider appropriate or desirable.

#### Item 6. Exhibits

See Index to Exhibits.

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

#### INSPIREMD, INC.

Date: November 12, 2013

By: /s/ Alan Milinazzo Name: Alan Milinazzo Title: President and Chief Executive Officer

By: /s/ Craig Shore

Name: Craig Shore Title: Chief Financial Officer, Secretary and Treasurer

### EXHIBIT INDEX

<u>Exhibit No.</u> 3.1	<b>Description</b> Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2012)
3.4	Certificate of Designation, Preferences and Rights of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
10.1*	Master Services Agreement, dated May 31, 2013, by and between InspireMD Ltd. and Medpace, Inc.
10.2*	Second Amendment to License Agreement, dated August 22, 2013, by and among, Svelte Medical Systems, Inc., InspireMD Ltd. and InspireMD, Inc.
10.3	Nonqualified Stock Option Agreement, dated September 3, 2013, by and between InspireMD, Inc. and Campbell Rogers (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on September 9, 2013)
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101**	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, formatted in XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements

<sup>\*</sup> Filed herewith.

\*\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

This **Master Services Agreement** (the "Agreement"), dated as of 31 May 2013 (the "Effective Date"), is between **Medpace, Inc.,** an Ohio Corporation with a principal place of business at 5375 Medpace Way, Cincinnati, OH 45227 ("MEDPACE") and **InspireMD Ltd., a** a company organized under the laws of the State of Israel Corporation with a principal place of business at 4 Menorat Hamaor, Tel Aviv, Israel, ("SPONSOR"). MEDPACE and SPONSOR are sometimes referred to herein individually as a "Party" and together as the "Parties."

#### **RECITALS:**

WHEREAS, SPONSOR is in the business of developing and obtaining regulatory approval of the marketing and sale of pharmaceutical products and or biological products, and or medical devices; and

WHEREAS, MEDPACE is engaged in the business of providing services related to the design and execution of clinical development programs involving drugs, biologics, and medical devices through engagement by its clients, the sponsors of clinical development programs, to perform such services; and

WHEREAS, SPONSOR desires to engage MEDPACE to perform certain services ("Services") as set forth hereinafter in connection with certain clinical trials, all in accordance with and subject to the terms of this Agreement;

**NOW, THEREFORE,** in consideration of the premises and the mutual covenants and conditions hereinafter set forth, the Parties agree as follows:

#### 1. PROJECT SPECIFICATIONS

- A. MEDPACE hereby agrees to perform Services for SPONSOR from time to time. The precise Services to be performed by MEDPACE shall be mutually agreed upon by the Parties and set forth in one or more task orders (each a "Task Order"), a form of which is attached hereto as Exhibit A. Each Task Order shall be signed by an authorized representative of each Party and shall include detailed information concerning a given project, including a description of the specific services to be provided ("Scope of Work"), project milestones and target completion dates ("Project Schedule"), a detailed budget ("Project Budget"), and a schedule of payments related to the Project Schedule and the Project Budget ("Payment Schedule"). Each Task Order shall contain a Transfer of Obligations list ("Transfer of Obligations") in conjunction with the relevant Task Order and consistent with the regulations set forth in 21 C.F.R. Section 312, Subpart D (Responsibilities of Sponsors and Investigators). Any responsibilities not specifically transferred in the Transfer of Obligations shall remain the regulatory responsibility of SPONSOR.
- B. Unless otherwise stated in the applicable Task Order, the Services will be conducted in compliance with MEDPACE SOPs and Policies.
- C. From time to time, SPONSOR may wish to enter into a Task Order with a MEDPACE Affiliate for Services under this Agreement ("Affiliate Task Order"), and such MEDPACE Affiliate may wish enter into the Affiliate Task Order with SPONSOR. Any such Affiliate Task Order must be in writing and signed by the parties to the Affiliate Task Order, and each signatory to an Affiliate Task Order is solely responsible for all obligations it undertakes under the Affiliate Task Order, and Order. For the purposes of a particular Affiliate Task Order, the Affiliate signing such Affiliate Task Order will be substituted for MEDPACE everywhere it appears in this Agreement, and the term "Affiliate Task Order" will be substituted for Task Order everywhere it appears in this Agreement.

- D. As used herein, "Affiliate" means in relation to a Party, any entity, directly or indirectly, controlling such Party, controlled by such Party, or under common control with such Party.
- E. As part of the Services and as an accommodation to SPONSOR, MEDPACE may contract with third parties for the provision of services not customarily performed or provided by MEDPACE ("Pre-funded Vendors"). While MEDPACE may contract with and/or facilitate the activities of such Pre-funded Vendors, MEDPACE does not undertake by virtue of this Agreement, the relevant Task Order or such third party contract, responsibility for the Pre-funded Vendor's business, professional conduct, performance, or breaches by such Pre-funded Vendors. MEDPACE's responsibility with respect to such Pre-funded Vendors shall be to coordinate the services of such Pre-funded Vendors and to make payments after receipt of sufficient funds from SPONSOR ("Pre-funded Expenses"). If sufficient funds are not received from SPONSOR, payments to Pre-funded Vendors may be delayed. Pre - funded Expenses may include but are not limited to third party advance payments for investigator meetings, vendors, Study Site payments ("Study Site" shall mean the physical location at which a particular investigator conducts a study), and any payments to investigators, institutions, and site maintenance organizations for services performed that relate to a study. In the event a Pre-funded Vendor requests indemnification with respect to the services performed under such Pre-funded Vendor's contract, MEDPACE shall notify SPONSOR and SPONSOR shall, at its discretion, enter into an indemnification agreement directly with such Pre-funded Vendors. MEDPACE shall have no obligation with respect to the indemnity of a Pre-funded Vendors. The Parties acknowledge and agree that any Pre-funded Vendors (including but not limited to investigators, institutions or site management organizations) paid with Pre-funded Expenses in connection with the performance of Services under this Agreement or any Task Order shall not be considered the agent, employee or subcontractor of MEDPACE.
- F. Except as otherwise agreed by the Parties in writing, SPONSOR is and at all times remains, in all geographical regions where the Study is being performed, the "Sponsor" or "Legal Representative" of the Study pursuant to or applicable law.

#### 2. PROJECT SCHEDULE

A. Each Task Order shall contain project timelines, milestones or target dates for completion of a project or a portion thereof, and all such schedules shall be reasonable for the Services to be provided. In all events, the Parties shall use their reasonable best efforts to comply with each Task Order.

B. If at any time either Party anticipates a delay in meeting the timelines for a given Task Order as set forth in its Project Schedule, either due to changes to the Services requested by SPONSOR, or other causes (such as FDA approval of a competitor's NDA for the same drug, which may adversely affect patient enrollment), then the anticipating Party shall promptly notify the other Party in writing, specifying the reason for the delay and the anticipated effect upon the timelines, milestones or other deliverables.

#### **<u>3. CONTRACT AMENDMENTS</u>**

Any change in the details of a Task Order or the assumptions upon which the Task Order is based may require changes in the Project Budget, Payment Schedule or Project Schedule. Every such change shall require a written amendment to the Task Order (a "Contract Amendment"). Each Contract Amendment shall detail the requested changes to the applicable task, responsibility, duty, budget, timeline or other matter. The Contract Amendment will become effective upon the execution of the Contract Amendment by both Parties, and if applicable, will specify the period of time within which MEDPACE must implement the changes. Both Parties agree to act in good faith and promptly when considering a Contract Amendment shall become effective unless and until it is signed by both Parties. Any such changes that result in additional charges shall be reflected in the Contract Amendment to the affected Task Order, Project Budget or Payment Schedule.

#### 4. PROJECT BUDGET, PAYMENT SCHEDULE, AND TERMS

A. Service Fees:

The SPONSOR agrees to pay MEDPACE for Services rendered pursuant to the Project Budget and Payment Schedules included in each Task Order. The Parties understand and agree that the Service Fee shall be included in each respective Task Order's project budget as a fixed fee. All Service Fees are fixed costs unless the underlying assumptions change, including but not limited to, trial duration, number of investigative sites, number of patients, and services provided by Medpace. All such changes shall be documented in a Contract Amendment.

B. Pass Through Costs:

The SPONSOR agrees to reimburse MEDPACE for reasonable pass-through costs identified in the Task Order and incurred by MEDPACE in providing the Services in accordance with the relevant Task Order ("Pass-through Costs"). Pass-through Costs may include, but are not limited to, CRF printing costs, project-specific printing, shipping, copying and binding costs, telecommunication and data costs, travel costs, including subsistence and accommodation costs in compliance with the Medpace travel policy, literature search and article retrieval costs, translation costs, EC/regulatory fees, and pharmacy fees. All expenses billed to SPONSOR by MEDPACE must be accompanied by appropriate documentary evidence, such as receipts or other documentation reasonably acceptable to SPONSOR. The Parties understand and agree that the Pass-Through Costs shall be included in each respective Task Order's project budget as a good faith estimate. If it becomes apparent to MEDPACE during the performance of its duties under a Task Order that that amount estimated for these Pass-Through Costs will be exceeded, it will notify SPONSOR and seek approval for the excess expense amount before it is incurred. The Parties acknowledge that an email from SPONSOR approving such excess expenses shall be sufficient approval. SPONSOR will be responsible for the payment of such excess Pre-funded expense only if it approved such excess expense.

Medpace, Inc.

C. Pre - funded Expenses:

The Parties will work to establish a process for payment of Pre-funded Expenses in the applicable Task Order which allows for timely payment of such funds to Pre-funded Vendors. The Parties understand and agree that the Pre-funded Expenses will be included in each respective Task Order's project budget as a good faith estimate. If it becomes apparent to MEDPACE during the performance of its duties under a Task Order that that amount estimated for these Pre-funded Expenses will be exceeded, it will notify SPONSOR and seek approval for the excess expense amount before it is incurred. The Parties acknowledge that an email from SPONSOR approving such excess expenses shall be sufficient approval. SPONSOR will be responsible for the payment of such excess Pre-funded expense only if it approved such excess expense.

D. Payment Terms:

Unless otherwise agreed to in the applicable Task Order, SPONSOR shall mail payments to MEDPACE within 45 days after receipt of a written invoice and required supporting documentation as applicable ("Payment Period"). An annual interest rate equal to the lesser of 18% or the maximum amount allowed by applicable law will be applied to outstanding invoices greater than 60 days after receipt of a written invoice. The Parties will work in good faith to establish a payment schedule in the applicable Task Order to ensure that MEDPACE is kept in a cash neutral position and to avoid a negative cash flow at any time during the term of the applicable Task Order.

E. Security:

If at any time and from time to time during the term of the Agreement or any Task Order, MEDPACE shall determine that there are reasonable grounds for insecurity on the part of MEDPACE as to the ability of SPONSOR to meet its financial obligations hereunder as they become due, MEDPACE and SPONSOR shall agree upon the appropriate amount and form of security to be provided by SPONSOR. SPONSOR shall provide such security within thirty (30) days of MEDPACE's request.

Medpace, Inc.

#### 5. WARRANTIES AND REPRESENTATIONS:

- A. Acknowledgements:
  - i. MEDPACE acknowledges that the Services to be provided hereunder are for the benefit of, and are subject to the direction of SPONSOR. MEDPACE acknowledges that SPONSOR is the beneficiary under the terms of this Agreement and each Task Order, and that SPONSOR is entitled to enforce the provisions thereof.
  - ii. In carrying out its responsibilities under this Agreement and each Task Order, neither Party nor it nor any of its respective representatives will pay, offer or promise to pay, or authorize the payment of, any money, or give or promise to give, or authorize the giving of, any services or anything else of value, either directly or through a third party, to any official or employee of any governmental authority or instrumentality, or of a public international organization, or of any agency or subdivision thereof corruptly for the purpose of improperly (i) influencing any act or decision of that person in his official capacity, including a decision to fail to perform his functions with such governmental agency or instrumentality or such public international organization or such political party, (ii) inducing such person to use his influence with such governmental agency or instrumentality or such public international organization or such public party to affect or influence any act or decision thereof or (iii) securing any improper advantage; provided however, the foregoing representation shall not apply to any facilitating or expediting payment to a foreign official, political party, or party official the purpose of which is to expedite or to secure the performance of a routine governmental action by a foreign official, political party, or party official.
- B. Representations and Warranties of MEDPACE:
  - i. MEDPACE represents and warrants that it is duly organized, validly existing and in good standing in its place of organization, and is in good standing in and duly qualified to do business.
  - ii. MEDPACE warrants that the execution, delivery and performance of this Agreement and each task order has been validly authorized by all corporate action and this Agreement and each Task Order represents the valid binding agreement of MEDPACE enforceable in accordance with its terms. The execution, delivery and performance of this Agreement and each Task Order will not violate any organizational document governing MEDPACE, any agreement to which MEDPACE is a party, or any law or court or governmental order, holding or writ by which MEDPACE is bound. MEDPACE further warrants that it shall render the Services requested by SPONSOR in accordance with high professional standards, consistent with Good Clinical Practices and with the standard of care customary in the contract research organization industry.

- iii. MEDPACE warrants that the personnel assigned to perform services rendered under this Agreement shall be qualified and professionally capable of performing the Services, shall be adequate to effectively perform the Services on the agreed upon schedule and shall devote such time as is necessary to perform the Services on such agreed upon schedule.
- iv. MEDPACE further warrants that it shall perform the Services in compliance with all applicable laws and regulations including, without limitation, the Federal Food, Drug and Cosmetic Act and the regulations (as amended) promulgated pursuant thereto, and all future amendments during the term and European Standard ISO 14155:2011: Clinical Investigation of Medical Devices for Human Subjects, and as per the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964 and later revisions. MEDPACE further warrants that it shall make available to SPONSOR, or to the responsible regulatory authority, relevant records, programs and data as may reasonably be requested by SPONSOR or which is the subject of a Task Order. SPONSOR shall have the right to monitor the operations of MEDPACE hereunder, and SPONSOR representatives shall have the right to visit any of the facilities where MEDPACE is performing any of the Services and during such visits to inspect the work being done and materials used, to observe the procedures being followed, to examine the books, records and other data relevant to the Services. If any regulatory agency requests to inspect any books, records, data of MEDPACE relating to the Services, MEDPACE shall immediately notify SPONSOR.
- v. MEDPACE represents and warrants that there is no litigation, regulatory investigation or proceeding, administrative hearing or any other similar proceeding pending or to the best of its knowledge threatened against MEDPACE which could adversely affect MEDPACE's ability to perform the Services.
- C. Representations and Warranties of SPONSOR
  - i. SPONSOR represents and warrants that it is a corporation with its principal office and place of business at 4 Menorat Hamaor, Tel Aviv, Israel duly organized, validly existing and in good standing in its place of organization, and is in good standing in and duly qualified to do business.
  - ii. SPONSOR warrants that the execution, delivery and performance of this Agreement and each Task Order has been validly authorized by all corporate action and this Agreement and each Task Order represents the valid binding agreement of SPONSOR enforceable in accordance with its terms. The execution, delivery and performance of this Agreement and each Task Order will not violate any organizational document governing SPONSOR, any agreement to which SPONSOR is a party, or any law or court or governmental order, holding or writ by which SPONSOR is bound.

- iii. SPONSOR represents and warrants that there is no litigation, regulatory investigation or proceeding, administrative hearing or any other similar proceeding pending or to the best of its knowledge threatened against SPONSOR which could adversely affect SPONSOR's ability to perform under this Agreement or any Task Order.
- iv. Annually SPONSOR shall provide a copy of a certificate evidencing its insurance coverage to MEDPACE.

#### 6. TERMINATION

- A. Either Party may terminate this Agreement without cause upon giving the other Party sixty (60) notice of such termination unless otherwise agreed to by the Parties, provided such termination shall not in and of itself affect any then uncompleted Task Order.
- B. SPONSOR may terminate any Task Order without cause upon giving MEDPACE sixty (60) notice of such termination unless otherwise agreed to by the Parties.
- C. MEDPACE may terminate a Task Order only if SPONSOR has defaulted on its obligations thereunder and (i) if the default is the failure of SPONSOR to pay MEDPACE within the Payment Period as set forth in Section 4(D) above and has not cured such default within 15 days of its receipt of MEDPACE's notice of default; and (ii) if the default is based on any beach other than that set forth in section 6(C)(i) and SPONSOR has not cured such default within 30 days after SPONSOR's receipt of MEDPACE's written notice of the default.
- D. As soon as practicable after receipt of such termination notice, the Parties shall cooperate in good faith to agree on a plan to expeditiously conclude activities with respect to such matter, including transfer of all case report forms, study files, and other data and information in any and all formats available, including electronic format and computer files and programs, in MEDPACE's possession to SPONSOR.
- E. In the event of any termination of a Task Order before completion, SPONSOR agrees to pay MEDPACE for all Services rendered pursuant to the unfinished Task Order prior to such termination and any non-cancelable expenses incurred in connection with MEDPACE's performance of Services thereunder. As soon as reasonably practicable following receipt of a termination notice, MEDPACE shall submit an itemized accounting of Services performed, expenses incurred pursuant to performance of the Services, non-cancelable expenses incurred by MEDPACE relating to any unfinished Task Order, and payments received in order to determine a balance to be paid by either Party to the other. Such balance shall be paid within 30 days of receipt of such an itemized accounting by SPONSOR.

Medpace, Inc.

#### 7. COMMUNICATIONS

Any notice required or permitted under this Agreement shall be in writing and shall be deemed given if delivered personally, mailed by prepaid, first class, certified mail, return receipt requested, or sent by express courier service, to the Party to be notified at the addresses set forth below (or such other address as shall be designated by written notice); provided that all notices shall be effective upon receipt thereof:

If to MEDPACE:

Medpace, Inc. 5375 Medpace Way Cincinnati, OH 45227 Attn: August J. Troendle Telephone: (513) 579-9911 x2278

If to SPONSOR: Craig Shore Chief Financial Officer 4 Menorat Hamaor Tel Aviv, Israel

#### **8. CONFIDENTIALITY**

- A. SPONSOR, may provide confidential information to MEDPACE during the course of this Agreement. All information by SPONSOR or its clients or data collected by MEDPACE for SPONSOR during the course of performance of the Services is deemed to be the confidential information of SPONSOR ("SPONSOR Confidential Information"). MEDPACE shall not disclose SPONSOR Confidential Information to any third party, or use SPONSOR Confidential Information for any purpose other than for the benefit of SPONSOR, without the prior written consent of SPONSOR.
  - i. MEDPACE shall ensure by binding written agreement that its employees, agents, and approved independent contractors involved in the Services shall comply with the provisions of Article 8 of this Agreement. MEDPACE shall disclose SPONSOR Confidential Information only to those of its employees, agents, and independent contractors who reasonably need to know SPONSOR Confidential Information.
  - ii. MEDPACE shall exercise due care, but no less than a reasonable degree of care, to prevent the unauthorized disclosure and use of SPONSOR Confidential Information associated with the Services.
- B. MEDPACE may provide confidential information to SPONSOR during the course of this Agreement ("MEDPACE Confidential Information"). MEDPACE Confidential Information shall include but is not limited to standard operating procedures, pricing, and financial information provided by MEDPACE or its Affiliates to SPONSOR during the course of performance of the Services, and any non public information pertaining to MEDPACE's business practices or other proprietary information. SPONSOR shall not disclose MEDPACE Confidential Information to any third party, or use MEDPACE Confidential Information for any purpose other than for those set forth under this Agreement or a Task Order, without the prior written consent of MEDPACE.

- i. SPONSOR shall ensure by binding written agreement that its employees, agents, and approved independent contractors involved in the Services shall comply with the provisions of Article 8 of this Agreement. SPONSOR shall disclose MEDPACE Confidential Information only to those of its employees, agents, and independent contractors who reasonably need to know MEDPACE Confidential Information.
- ii. SPONSOR shall exercise due care, but no less than a reasonable degree of care, to prevent the unauthorized disclosure and use of confidential information associated with the Services.
- C. SPONSOR Confidential Information and MEDPACE Confidential Information shall hereinafter be referred to as "Confidential Information".
- D. This confidentiality and nondisclosure provision shall not apply to:
  - i. Confidential Information which was known by the Party before the date hereof or which is independently discovered, after the date hereof, without the aid, application or use of the Confidential Information, as evidenced by written records;
  - ii. Confidential Information which is in the public domain on the date hereof or subsequently becomes publicly available through no fault or action of the other Party; or
  - iii. Confidential Information, which is disclosed to the Party by a third party, authorized to disclose it.
- E. If the receiving Party is requested to disclose the Confidential Information of the other Party or the substance of this Agreement in connection with a legal or administrative proceeding or otherwise to comply with a requirement under the law, the receiving party will give the disclosing Party prompt notice of such request so that the disclosing Party may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. The disclosing Party must notify the receiving Partywithin 5 business days that it intends to take action in response to the request for disclosure. If the disclosing Party seeks a protective order or other remedy, the receiving Party, at the disclosing Party's expense, will cooperate with and assist the disclosing Party in such efforts. Failure of the disclosing Party to intervene shall not relieve the obligations to maintain confidentiality except in so far as the receiving Party must comply with the terms of such process compelling disclosure.
- F. The Parties acknowledge and agree that the disclosure of Confidential Information (as contemplated in this Section 8) to third parties not permitted in this Section 8 would result in hardship, loss, irreparable injury and damage to the non-breaching Party and that the non-breaching Party has a legitimate interest in protecting its Confidential Information and its business goodwill. The Parties acknowledge that a remedy at law for any breach by the non-breaching Party of this provision will be inadequate, and the breaching Party hereby agrees that the non-breaching Party shall be entitled, without the necessity of posting a bond of cash or otherwise, to injunctive relief in case of any such breach in addition to all other relief that may be available to the non-breaching Party. This covenant not to disclose the Confidential Information survives termination of this Agreement.

Medpace, Inc.

#### 9. RIGHTS IN PROPERTY

- A. All materials, documents, data, software and information of every kind and description supplied to MEDPACE by SPONSOR or any of SPONSOR's clients, or prepared, developed, or generated by MEDPACE pursuant to this Agreement, (except for the preexisting MEDPACE procedural manuals, personal data, methods, procedures, and policies) are and shall be the sole and exclusive property of SPONSOR. Further, all data and information generated or derived by MEDPACE as the result of services performed by it under this Agreement shall be and remain the exclusive property of SPONSOR. SPONSOR shall have the right to make whatever use they deem desirable of any such materials, documents, data or software. MEDPACE shall not, without the prior written consent of SPONSOR, publish, disseminate, or otherwise disclose to any third party any such property (except such disclosure as may be required by law), or use any such property for any purpose other than the performance of this Agreement. Any inventions or other intellectual property, including without limitation protectable copyrights and trademarks, that may evolve from the data and information described above or as the result of Services performed by MEDPACE under this Agreement shall belong to SPONSOR and MEDPACE agrees to assign its rights in all such inventions and/or other intellectual property to SPONSOR and MEDPACE agrees to forth in Article 10 below.
- B. SPONSOR acknowledges that all computer programs, software, applications, databases, proposals and other documentation generally used by MEDPACE and not directly related to, derived from or developed solely for SPONSOR are the exclusive and confidential property of MEDPACE or the third parties from whom MEDPACE has secured the right of use. SPONSOR agrees that any improvement, alteration or enhancement to MEDPACE systems, software, applications or processes which are developed or implemented during the course of any Services performed hereunder, without the use of any SPONSOR data, information, materials or Confidential Information (or derivatives thereof), shall be the property of MEDPACE.

#### 10. PATENT RIGHTS

MEDPACE shall disclose promptly to SPONSOR any and all inventions, discoveries and improvements conceived or made by MEDPACE while providing such services to SPONSOR pursuant to the Agreement and constituting a modification or extension of use relating to SPONSOR's proprietary rights, and agrees to assign all its interest therein to SPONSOR or its nominee; whenever requested to do so by SPONSOR, MEDPACE shall execute any and all applications, assignments, or other instruments and give testimony which SPONSOR shall deem necessary to apply for and obtain a patent in the United States of America and/or other applicable jurisdiction or of any foreign country or to protect otherwise SPONSOR's interests and shall compensate MEDPACE for the time devoted to said activities and reimburse it for reasonable expenses incurred provided that MEDPACE has not been compensated for such activites, costs and expenses under any prior or existing Task Order(s).

#### 11. PUBLICITY

- A. MEDPACE shall not make any public announcements concerning this Agreement or the subject matter hereof without the prior written consent of SPONSOR.
- B. SPONSOR may not use MEDPACE's name, logo or trademark in any communication, release, notice or other publication without the express prior written consent of MEDPACE.

#### 12. SECURITY AND DISPOSITION OF STUDY AND PATIENT FILES

- A. MEDPACE shall use commercially reasonable efforts, including, but not limited to, periodic backup of computer files, to prevent the loss or alteration of SPONSOR's study data, Confidential Information, documentation, and correspondence. MEDPACE shall in all respects comply with any Food and Drug Administration regulations concerning the maintenance, creation and storage of records, including electronic records.
- B. At appropriate time points or at completion of Services under a Task Order, MEDPACE shall transfer study materials, documents and correspondence to SPONSOR. MEDPACE shall have the right to retain one copy of any study materials, documentation, and correspondence necessary solely to meet regulatory or MEDPACE's own internal audit requirements, so long as it continues to maintain the confidentiality requirements of Article 8.
- C. To the extent required by applicable law, the Parties agree to comply with all applicable state and Federal laws regarding the privacy of protected health information and shall, when and if required, enter into a federal Health Insurance Portability and Accountability Act ("HIPAA") Business Associate Agreement for purposes of this Section 12.

#### 13. SPONSOR OBLIGATIONS

SPONSOR acknowledges that performance of the Services by MEDPACE will require the co-operative involvement of both Parties, and SPONSOR hereby agrees to provide such assistance as may be reasonably necessary to enable MEDPACE to perform the Services.

Medpace, Inc.

#### 14. INDEMNIFICATION

- A. SPONSOR shall indemnify, defend and hold harmless MEDPACE from and against any and all damages, losses, liabilities, costs or expenses (collectively "Damages"), resulting or arising from any third-party claims, demands, assessments, actions, suits, investigations or proceedings (collectively "Claims"), relating to or arising from or in connection with this Agreement or the Services under any Task Order (including but not limited to any Damages arising from or in connection with any study, test, device, product or potential product to which this Agreement relates), to the extent such Claims or Damages have not resulted from MEDPACE's negligence, willful misconduct, or breach of any applicable law or material breach of this Agreement or any Task Order by MEDPACE.
- B. MEDPACE agrees to indemnify, defend and hold harmless SPONSOR from and against any and all Damages resulting or arising from third-party Claims relating to or arising from or in connection with the Services under any Task Order to the extent that such Claims or Damages are determined to have resulted from the negligence or willful misconduct of MEDPACE or a breach of any applicable federal, state or local law or a material breach of this Agreement or any Task Order by MEDPACE.
- C. Any party providing indemnification under this Agreement shall have the right to control the defense and settlement of any Claims or Damages. The indemnified party shall have the right to obtain separate legal counsel at its own expense if it so chooses. The indemnifying party shall not unreasonably withhold consent for settlement and the indemnified party shall reasonably cooperate in the defense of any Claims or Damages and provide prompt notice to the indemnifying party of any Claims or Damages for which indemnification is sought.

#### 15. LIMITATION OF LIABILITY

Notwithstanding the terms of Article 14 above, in no event shall SPONSOR or MEDPACE be liable for any indirect, incidental, special, or consequential damages or lost profits arising out of the provision of services hereunder, even if the breaching party has been advised of the possibility of such damages.

#### 16. INSPECTIONS AND AUDITS

A. SPONSOR shall have the right, upon at least ten (10) days' prior written notice to MEDPACE, to examine the standard operating procedures, facilities, books, records, papers, files and documentation, including computer files, data bases and records, at MEDPACE's facilities and the facilities of clinical investigators contracted by MEDPACE to determine the adequacy of such records, to ensure the Services are being performed in accordance with the approved Task Orders and applicable regulations and/or to examine the financial records of MEDPACE as may be reasonably necessary to verify out-of-pocket expenses incurred during the performance of the Services. Such inspections and audits shall be conducted during normal business hours.

- B. MEDPACE shall provide reasonable assistance, including making available members of its staff and providing access to all requested records, to facilitate such inspections and audits.
- C. MEDPACE shall take all reasonable steps required by SPONSOR to cure any deficiencies found in any audit, inspection or investigation.

#### 17. DEBARMENT

- A. MEDPACE hereby represents, warrants, and certifies that neither it nor any of its officers, directors, owners, principals or employees has been or will be at any relevant time hereunder debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §335a(a) or (b), or similar local law. In the event that any such party becomes debarred, MEDPACE shall notify SPONSOR in writing immediately.
- B. MEDPACE hereby represents, warrants, and certifies that it has not and shall not use in any capacity the services of any individual, corporation, partnership, or association which has been debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §335a(a) or (b), or similar local law. In the event MEDPACE becomes aware of or receives notice of the debarment of any individual, corporation, partnership, or association providing services to MEDPACE, which relate to the Services being provided under this Agreement, MEDPACE shall notify SPONSOR in writing immediately.

#### 18. NON SOLICITATION

Neither Party and its Affiliates shall during the term of this Agreement and for a period of twelve months following its termination, either directly or indirectly, hire any employee of the other Party with whom its comes into contact as a result of providing the Services, or recruit, solicit, or entice any such person to become employed by it or any Affiliate and shall not approach any such employee for such purpose or encourage, authorize or approve the taking of such action by any other person. The Parties agree that any breach of this provision would cause irreparable harm and that in addition to any and all other available remedies injunctive relief, without the necessity of a bond or other security, shall be appropriate and available.

#### 19. ENTIRE AGREEMENT

This Agreement contains the full understanding of the Parties with respect to the subject matter hereof and supersedes all existing agreements and all other oral, written or other communications between the Parties concerning the subject matter hereof. This Agreement shall not be amended, modified or supplemented in any way except in writing and signed by a duly authorized representative of SPONSOR and MEDPACE.

Medpace, Inc.

#### 20. GOVERNING LAW

This Agreement and the performance hereof shall be governed, interpreted and construed in all respects by the internal laws of the State of Ohio. All disputes and claims arising under this Agreement or any Task Order shall be resolved exclusively in a court of applicable jurisdiction located in Cincinnati, Ohio and each party consents to the venue of any such action.

#### 21. NO WAIVER

No waiver of any term, provision, or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provisions, or conditions, or of any other term, provision, or condition of this Agreement.

#### 22. INDEPENDENT CONTRACTOR

In fulfilling its obligations pursuant to this Agreement, each Party shall be acting as an independent contractor. Neither Party is granted any right or authority to assume or to create any obligation or responsibility, expressed or implied, on behalf of or in the name of the other Party.

#### 23. FORCE MAJEURE

Neither Party shall be liable or deemed to be in default for any delay due to causes beyond the reasonable control of the Party, such as: war, acts or threats of terrorism, civil disorders, acts of God, or government action; provided, that the affected Party promptly notifies the other of the cause and its effects on the Services to be performed hereunder. Financial difficulty shall never be deemed a force majeure event.

#### 24. SEVERABILITY

In the event any provision of this Agreement shall be determined to be void or unenforceable, the remaining provisions shall remain in full force and effect.

#### 25. ASSIGNMENT

- A. Except as set forth herein, neither Party shall assign this Agreement or any Task Order except with the express prior written consent of the other Party.
- B. Notwithstanding anything contained herein, a Party may assign this Agreement and/or any Task Order to a Successor.

#### 26. SUBCONTRACTING

MEDPACE may subcontract any portion of the Services hereunder to an Affiliate without the prior written consent of SPONSOR, provided MEDPACE remains liable for the performance of any such Affiliate. MEDPACE will not subcontract any portion of the Services hereunder to any party other than a MEDPACE Affiliate without prior written consent of SPONSOR.

Medpace, Inc.

#### 27. CONFLICTS BETWEEN AGREEMENTS

In the event that there is any conflict between the provisions of this Agreement and any duly executed Task Order, this Agreement shall control, unless the Task Order clearly states that in the event of such conflict, it shall control.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

#### **MEDPACE, INC.**

By: <u>/s/ John Wynne</u> Name: John Wynne Title: Executive Director, Business Development Support

INSPIREMD LTD.

By: <u>/s/ Alan Milinazzo</u> Name: Alan Milinazzo Title: Chief Executive Officer

#### SECOND AMENDMENT TO LICENSE AGREEMENT

This Second Amendment (this "Second Amendment") to the License Agreement is now entered into as of August 22, 2013, by and among Svelte Medical Systems, Inc., a Delaware corporation having its principal place of business at 657 Central Avenue, New Providence, New Jersey 07974 ("Svelte," or "Licensor"); InspireMD Ltd., an Israeli corporation having its principal place of business at 4 Menorat Hamor St., Tel Aviv, Israel L3 67448 ("InspireMD," or "Licensee"); and InspireMD, Inc., a Delaware corporation and the sole stockholder of Licensee ("InspireMD US"). Licensor, Licensee and InspireMD US are hereinafter individually referred to as a "Party," and collectively referred to as the "Parties."

#### **RECITALS**

WHEREAS, Licensor and Licensee have entered into that certain License Agreement dated March 19, 2010, as supplemented by that certain letter dated March 15, 2010 (the "*License Agreement*"); and

WHEREAS, Licensor and Licensee have entered into that certain First Amendment to License agreement dated October 20, 2012 (the "First Amendment"); and

WHEREAS, capitalized terms used but not defined herein shall have the meanings attributed to such terms in the License Agreement and First Amendment; and

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and obligations set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

#### **1. MISCELLANEOUS.**

(a) Construction. The terms of this Second Amendment amend and modify the First Amendment and License Agreement as if fully set forth in the License Agreement. If there is any conflict between the terms, conditions and obligations of this Second Amendment and the First Amendment or License Agreement, this Second Amendment's terms, conditions and obligations shall control. All other provisions of the First Amendment or the License Agreement not specifically modified by this Second Amendment are preserved. This Second Amendment may be executed in counterparts (including via facsimile or .pdf), each of which shall be deemed an original, and all of which together shall constitute one and the same document.

#### 2. Amendments to the License Agreement.

(a) Section 3.2 of the First Amendment is hereby deleted in its entirety and replaced with the following:

SECOND AMENDMENT TO LICENSE AGREEMENT

#### " 3.2 ROYALTY & OTHER LICENSING FEE.

(a) Licensee shall pay Licensor \$192,000 representing advanced payment of a royalty in the aggregate amount of two percent (2%) of Net Sales for the period from July 1, 2013 through June 30, 2015, which amount assumes Net Sales of \$1.2 million per quarter (or \$9.6 million over the next eight quarters) from July 1, 2013 through June 30, 2015.

(b) Within forty five (45) calendar days following June 30, 2015, Licensee shall pay Licensor, retroactively, a royalty in the aggregate amount of two and one-half percent (2.5%) of Net Sales for any Net Sales in excess of \$10.56 million for the period from July 1, 2013 through June 30, 2015.

(c) Beginning July 1, 2015, Licensee shall pay Licensor a royalty in the aggregate amount of two and nine-tenths percent (2.9%) of Net Sales."

SIGNATURES ON THE FOLLOWING PAGE

SECOND AMENDMENT TO LICENSE AGREEMENT

IN WITNESS WHEREOF, each Party has caused its name to be hereunto subscribed, by its duly authorized officer as of the date indicated above.

LICENSOR:

**SVELTE MEDICAL SYSTEMS, INC.** 

By: /s/ Mark Pomeranz

Name: Mark Pomeranz Title: COO LICENSEE:

INSPIREMD LTD.

By: <u>/s/ Craig Shore</u> Name: Craig Shore Title: Chief Financial Officer

**INSPIREMD US:** 

INSPIREMD, INC.

By: <u>/s/ Craig Shore</u> Name: Craig Shore Title: Chief Financial Officer

SECOND AMENDMENT TO LICENSE AGREEMENT

#### CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alan Milinazzo, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of InspireMD, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 12, 2013

/s/ Alan Milinazzo Alan Milinazzo Chief Executive Officer

#### CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Craig Shore, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of InspireMD, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 12, 2013

/s/ Craig Shore Craig Shore Chief Financial Officer

#### CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended September 30, 2013 of InspireMD, Inc. (the "Company"). I, Alan Milinazzo, the Chief Executive Officer of the Company, certify that, based on my knowledge:

- (1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: November 12, 2013

By: /s/ Alan Milinazzo Name: Alan Milinazzo Title: Chief Executive Officer

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

#### CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended September 30, 2013 of InspireMD, Inc. (the "Company"). I, Craig Shore, the Chief Financial Officer and Principal Financial Officer of the Company, certify that, based on my knowledge:

- (1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: November 12, 2013

By: <u>/s/ Craig Shore</u> Name: Craig Shore

Title: Chief Financial Officer

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.